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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,701	10/23/2000	Jang B. Rampal	1956-045	9837

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PATENT LEGAL DEPARTMENT/A-42-C
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EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/694,701	Applicant(s) Rampal et al.
	Examiner Joyce Tung	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 18, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-66 and 68-70* is/are pending in the application.

4a) Of the above, claim(s) *1-28 and 43-54* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *29-42, 55-66, and 68-70* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-66 and 68-70* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2002 has been entered. Claims 1-66 and 68-70 are pending. The rejection and/or objection not reiterated from the previous office action are hereby withdrawn. The following rejection s and/or objections are either newly applied of reiterated.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 29-34, 36-38, 41-42, 55-56 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Varma (5,622,826).

Varma discloses immobilizing molecules on surface of platinum, glass or aminated polypropylene (See column 2, lines 48-51). The invention is directed to a method for immobilizing nucleic acid on a platinum surface (See column 2, lines 62-63). Varma also discloses that a hybridization experiment is performed on a platinum surface containing immobilized probes. The probe can be labeled and derivatized or non derivatized (See column 4, lines 36-41). The hybridization complex with labels is detected (See column 4, lines 47-56). The oligonucleotide probes are spotted on a platinum surface (typically 300nL per sport) and then the platinum chip is allowed to air dry at room temperature (See column 7, lines 49-59).
Thus, the teachings of Varma anticipate the limitations of claims 29-34, 36-38, 41-42, 55-56 and 63.

4. Claims 64-66 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Fareed et al. (4,970,144).

Fareed et al. disclose that a method of detecting a polypeptide contained in a sample comprising the steps of providing a modified substrate (See column 10, lines 19-29). A probe polypeptide that can form a complex with the target polypeptide, contacting either the probe or target polypeptide to a surface of the substrate to form a probe assay article or a target assay article, contacting the probe assay article or target assay article with the probe peptide or target peptides to form a complex comprising the probe and the target polypeptides and then detecting and determining the presence of the complex (See column 11, lines 34-57). A protein solution is air-dried on the bottoms of wells (See column 11, lines 43-43 and column 13, lines 65-68)) The

test antigen can be 10-100 nanogram (See column 11, lines 38-43). This teaching is inherent to the limitations of claim 68.

Since the claim language "modified substrate" is unclear what kind of modification made on the surface of the substrate. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26USPQ2d 1057 (Fed. Cir. 1993). Since Fareed et al. taught air-drying of a protein solution on the bottom of wells in microtiter dishes, the teachings of Fareed et al. anticipate the limitations of claims 64-66 and 68.

Thus, the teachings of Fareed et al. anticipate the limitations of claims 64-66 and 68.

Applicants argued that it is an unexpected discovery of the present invention. If it is an unexpected discover of the present invention that modified substrates, such as plasma-aminated polypropylene and polystyrene substrates are capable of direct and stable adsorption of polypeptides without the need for additional fix steps, the evidence regarding the unexpected results are required to be presented.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varma et al. (5,622,826) as applied to claims 29-34, 36-38, 41-42, 55-56 and 63 above, and further in view of Cremer et al. (6,197,501).

The teachings of Varma et al. are set forth in the section 3 above and Varma et al. do disclose fluorescence labeling and applying CCD camera.

Cremer disclose that the hybridization sample are detected by labeling the nucleic acid with fluorescent labels (See column 5, lines 8-16). CCD camera is used to detect the fluorescence signals (See column 5, lines 59-67).

One of ordinary skill in the art would have been motivated to apply fluorescence labeling on nucleic acid molecules and CCD camera to detect the fluorescence signals because with fluorochromium marked nucleic acid the sample sequence can be directly detected after washing steps. Thus, it would have been prima facie obvious to apply fluorescence labeling on nucleic acid molecules and CCD camera to detect the fluorescence signals.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varma et al. (5,622,826) as applied to claims 29-34, 36-38, 41-42, 55-56 and 63 above, and further in view of Rampal et al. (6,013,789).

The teachings of Varma et al. are set forth in the section 3 above and Varma does not disclose using the enzyme substrate to detect the polypeptide.

Rampal discloses a method for attaching pre-synthesized oligonucleotides to a polypropylene support medium which is aminated (as recited in claims 29-31 and 41-42) and that the invention is used to construct oligonucleotide arrays for hybridization assays (See the Abstract) (as recited claim 29 and 32-33). The labeling would be the biotinylation of a target or the detection oligonucleotide in which the biotin moieties bind to an avidin-enzyme conjugate (See column 9, lines 20-26) (as recited in claim 34). The label can also be fluorescent compounds (See column 9, lines 26-28) (as recited in claim 34). To detect biotinylated oligo target, the enzyme substrate, ELF, was used and the signals were detected by a CCD camera (See column 11, lines 13-27).

One of ordinary skill in the art would have been motivated to apply the enzyme substrate,ELF to the method of Varma because the detection by using the enzyme substrate, ELF as target by Rampal can be reached completion by 15 minutes (See column 11, lines 30-31). It would have been prima facie obvious to apply ELF detection method to the method of Varma.

8. Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varma et al. (5,622,826) and claims 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fareed et al. (4,970,144).

The teachings of Varma et al. are set forth in section 3 above and the teachings of Fareed et al. are set forth in section 4 above.

None of the references above discloses specifically the amount probe or target biopolymer contacted with the substrate, the aliquot amount of the probe or target needed, the time needed for drying as claimed.

However, it would have been prima facie obvious for an ordinary skill in the art at the time of the instant invention to modify the reaction condition of Varma et al. and Fareed et al. by optimizing the an amount of the probes or target biopolymers used and the time for air drying the target biopolymer on the surface of substrate because optimization of a reaction condition was routine practice in the art at the time of the instant invention. Moreover, since the amount of polynucleotide or polypeptide used as claimed is in a common range and the time needed for drying the sample is also in a common range it would have been prima facie obvious for an ordinary skill in the art to choose these concentration as claimed.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

JT

March 9, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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